IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors	:	Magnus Bolmsjö and Sonny Schelin
Serial No.	:	10/665,742
Filed	:	September 17, 2003
Title	:	Partial-Length Indwelling Prosthetic Catheter using Coiled Inflation Tube As an Anchor and Methods of Draining Urine and Flushing Clots
Group Art Unit	:	3761
Confirmation No.	:	4686
Examiners	:	Adam M. Marcetich and Leslie Deak

Declaration of Sonny Schelin, M.D., Ph.D.

I, Sonny Schelin M.D., Ph.D., declare that the following statements, made with respect to the above identified patent application, are of my own knowledge and are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above application or any patent issued thereon.

1. I am one inventor of the subject matter claimed in the above patent application.

2. A true and correct copy of my Curriculum Vitae is attached as an exhibit to this Declaration.

3. My medical specialties are urology and surgery.

4. I have assigned my interest in the invention described in the above patent application to ProstaLund Operations AB, a Swedish company, referred to below as "ProstaLund."

5. Under Swedish law as an inventor, I have a legal right to receive royalties and/or other compensation for commercial use the invention described in the above patent application. The amount of the royalty I receive is 4% of ProstaLund's sales of this device.

6. I also serve on a scientific advisory board of ProstaLund. In that capacity, I advise ProstaLund with respect to problems that may be encountered when medical doctors use ProstaLund's products, principally ProstaLund's "Core-Therm" trans-urethral microwave therapy (TUMT) device. ProstaLund's Core-Therm product applies microwave energy to the prostate gland from an antenna inserted within the urethra to heat and kill tissue in the prostate gland. Once the killed tissue sloughs off, the volume of the prostate gland is reduced. Reducing the volume of the prostate gland mitigates the effects of benign prostatic hyperplasia (BPH). BPH affects all older men to one degree or another, beginning at approximately age 50, with greater effects at increased age. Symptomatic BPH causes the prostate gland to swell. Because the urethra extends through the prostate gland, the swollen prostate gland constricts the urethra and reduces or even obstructs the flow of urine from the bladder. Reducing the volume of tissue in the prostate gland, by either killing the tissue using a treatment such as ProstaLund's "Core-Therm" TUMT or by excising tissue from the prostate gland in a mechanical surgical procedure known as a transurethral resection of the prostate (TURP), increases the size of the passage for urine to flow through the prostate gland and allows older men the ability to micturate or urinate in a more normal or effective manner. In addition, I also educate doctors on the proper use of ProstaLund's Core-Therm device. Most of my educational activities are with doctors located in Scandinavia, but I also educate doctors from other European countries. I perform these educational services by traveling to medical clinics throughout Scandinavia, and in my own clinic at Kalmar, Sweden. I have worked with ProstaLund in the capacity described in this paragraph for approximately the past 12 years. In connection with my advisory and educational services to ProstaLund, my clinic is compensated in the amount of about $3000 per month. Beyond this compensation, I have not been paid any extra for my time in preparing and giving this Declaration.

7. I own less than 1% of the shares of outstanding stock in ProstaLund. ProstaLund's stock is not publically traded so there is no certain market for the stock, but I estimate the total value of the stock that I now own to be about $2000.

8. I am not now an officer or director of ProstaLund. I derive no income or compensation from ProstaLund, except as described above in paragraphs 6 and 7.

9. Magnus Bolmsjö, Ph.D., and I worked together to develop the above invention and two other inventions of ProstaLund described in US patent applications 2005/0080399 and 2006/0111691. Dr. Bolmsjö is the inventor of ProstaLund's Core-Therm TUMT device and therapy, and I have worked with him in conjunction with that technology. Use of ProstaLund's Core-Therm TUMT requires inserting a catheter having a microwave antenna into the prostatic urethra and bladder neck, as well as through the rest of the urethra or urinary canal. Dr. Bolmsjö and I have worked together on hundreds BPH cases, and I have personally observed Dr. Bolmsjö's experience and understanding of the clinical effects of BPH and the use of catheters in the prostatic urethra and urinary canal. I believe that Dr. Bolmsjö fully understands and recognizes the effects and problems associated with the insertion of catheters in the prostatic urethra, because of our work together.

10. The catheter described in the above application offers many desirable advantages and improved aspects that I have not seen or had access to previously in my medical practice. The advantages and improvements of the catheter described in the above application are a benefit to both patients and medical practitioners alike. Many of those advantages and improvements result directly or indirectly from the coiled section of the inflation tube, as described below.

11. The coiled section of the inflation tube restrains against unintended movement or migration of the catheter body into and toward the bladder. Partial-length catheters must be kept in the desired position in the prostatic urethra. If a partial-length catheter migrates out of the prostatic urethra into the bladder, a significant medical procedure is typically required to remove or to reposition the catheter.

12. Some types of partial-length catheters experience a 30-50% incidence of unintended movement into the bladder. An emergency medical procedure must be performed either remove the catheter which has migrated from its intended position, or to otherwise reposition the catheter to the intended position. The patient may have to

wait hours before such an emergency procedure can be performed, during which time the patient is usually experiencing a severe level of pain due to pressure build-up of urine within the bladder. Preventing unintended migration eliminates the pain of medical procedures to correct the position of the catheter.

13. The trauma from a TUMT or other similar surgical procedure or other similar manipulation performed on the prostate gland usually causes the urinary canal through the prostate gland to swell closed, which prevents micturation. The trauma and the edema also inhibit the function of the external urinary sphincter muscle. To assure urine drainage from the bladder under these conditions, it is typical medical practice to insert a full-length catheter to assure urine drainage from the bladder out of the penis. Such a catheter must usually remain in place for approximately 3 weeks after these types of procedures. Because of the continually open urine passage through the full-length catheter, a urine collection bag must be connected to the catheter and worn by the patient. The emotional and physical difficulties associated with full-length catheters and urine collection bags causes most TUMT patients to remain at home out of the public to deal with the full-length catheter and urine drainage.

14. With the above catheter, the tube used to push the partial-length catheter into position can be left connected to the partial-length catheter to form a full-length catheter for a few days after the procedure. The connected partial-length catheter and push tube function as a full-length catheter to drain urine in the same way that a full-length catheter drains urine. Then, once the patient has made a modest level of recovery from the surgery to the point where control over external urinary sphincter muscle has been regained, the push tube is disconnected, leaving the partial-length catheter in place. The advantages of a partial-length catheter and a full-length catheter are thereby both obtained when the patient needs them the most. The patient has to endure the trauma from only a single insertion procedure, as compared to one procedure to insert a full-length catheter and another procedure to remove the full-length catheter and insert a partial-length catheter.

15. Use of the above catheter eliminates most of the emotional and other difficulties and discomfort caused by full-length catheters and urine collection bags. I have now routinely inserted catheters of the above invention in more than 200 patients after receiving Core-Therm TUMT treatment. After such a treatment, control over the external urinary sphincter muscle is usually present in about 80% of the patients, and the majority of the remaining 20% of the patients gain control within a few days thereafter. Use of the above catheter allows the patient to exercise self-control over micturation, while the partial-length catheter remains within the bladder neck and prostatic urethra to assure urine drainage through the tender, healing prostate gland. No urine collection bag is required because the patient is able to self-control urination through the urinary canal. No large tubes, valves and urine collection bags must be dealt with or worn by the patient. The small inflation tube extends from the urinary canal of the penis is not a significant discomfort or impediment to patients.

16. My experience with the above catheter is shown that most patients are able to return to work within three days after a TUMT procedure, because they feel comfortable emotionally and from a self-control standpoint, due to the above invention. Previously, when a full-length catheter was used, most patients did not return to work for almost 3 weeks following the procedure. Patients quickly learn and rely on selective self-control over micturation by use of the above catheter.

17. For previous partial-length catheters to be effective, their length had to be fairly precisely established. Normal physiological differences create variations in the length of the prostatic urethra, as described above. A relatively small gap between the downstream end of the catheter and the upstream end of the external urinary sphincter muscle of 3-4 mm, for example, may allow BPH or edema of the prostate gland to constrict sufficiently in that gap and prevent urine flow. Debris or other obstructive material sloughing off of the prostate gland after surgery can also accumulate in the gap and obstruct the passage for urine. For these reasons, it was previously necessary to precisely determine the length of the partial-length catheter so that its downstream

end would terminate just upstream of the external urinary sphincter muscle without any significant gap.

18. Determining the precise length of the catheter is difficult. Manual palpitation, measurement or feel, and x-ray and other imaging techniques are available to assist in determining the proper length, but such techniques are not entirely reliable because the patient may retain or wear the partial-length catheter differently from another patient with about the same length prostatic urethra or because the reduction of edema after prostate gland surgery may change the length of the prostatic urethra. For those patients who are not able to urinate after a partial-length catheter is inserted, because the length of that catheter is incorrect, it is necessary to perform a extraction procedure to remove the incorrect length catheter followed by a reinsertion procedure of a different correct-length catheter, all of which creates additional trauma to the patient.

19. With the above catheter, the coiled section of the inflation tube eliminates some of the difficulties of establishing a precise length for the catheter. The coiled section of the inflation tube does not have to be precisely and always located downstream of the external urinary sphincter muscle. If the coiled section is located or becomes located in the orifice through the external urinary sphincter muscle, that muscle can still constrict around the coiled section and terminate the flow of urine in a self-controlled manner. Thus, under circumstances where edema of the prostate gland or potential obstructions from biological material have subsided, a partial-length catheter will function adequately even though its length might be somewhat short. Furthermore, as the healing progresses following prostate surgery, the length of the prostatic urethra typically decreases. In this circumstance, a partial-length catheter having the desired final length to accommodate healing may be inserted immediately after the surgery, and the above catheter will still function adequately even though one of the coils might be located in the orifice of the external urinary sphincter muscle. Of course, after healing has progressed to the point where the urine drainage pathway through the prostate gland has diminished in length, the length of the partial-length catheter will turn out right to place the coiled section on the downstream side of the

external urinary sphincter muscle. For these reasons, the need for medical extraction and reinsertion of a different-length catheter after healing has started are almost completely eliminated, as a result of the above catheter.

20. Because the coiled section of the inflation tube will accommodate differences in length in the manner described in paragraph 19, there is no need to have a supply of catheters in many different lengths. Only a few different lengths of catheters are usually sufficient for all patients with different length prostatic urethras. Similarly, there is no need to incorporate a length adjustment mechanism in the main body of the partial-length catheter to assure the proper length of the catheter, for the same reasons.

21. In Sweden, the cost to the patient of using the above described partial-length catheter is relatively inexpensive, compared to the cost of using a stent to resolve acute urinary retention. Stents are relatively expensive, costing as much as 10 times the cost of the partial-length catheter described above, presently in Sweden. A medical doctor does not have to hesitate to use the above catheter on patients because of a concern about its price. I attribute the low cost of the above catheter to its simple and ingenious construction, using common and ordinarily-used catheter materials, and to its simplicity of insertion, removal and use.

22. Partial-length catheters offer significant medical benefits over full-length catheters. The big disadvantage to a full-length catheter is that it provides a continually open urine drainage passageway between the exterior of the patient and the interior of the bladder. The continually open urine drainage passageway of a full-length catheter allows germs to move into the bladder. Germs will move through a full-length catheter into the bladder within a few hours, where they create urinary tract infection (UTI). After a TUMT treatment, a full-length catheter will usually result in 30% of the patients having symptomatic UTI. When a partial-length catheter is used, the urinary tract through the penis retains its normal functionality, and offers natural protection against germs moving upward through the urethra in the penis into the bladder. The normal stream of

urine through the urinary tract counteracts the germs, keeping the germs from entering the bladder and providing natural protection against UTI.

23. In the above invention, the small inflation tube does not inhibit the normal protection against UTI from urine flow. The individual coils of the coiled section only contact a small area of the urethra, and there is space between those coils to allow the urine to flush germs out with the urine. Preventing or substantially reducing the incidence of UTI is a big advantage to the above catheter, and to partial-length catheters in general. Because the above partial-length catheter may be used successfully in many circumstances where full-length catheters were previously required, the benefits of the above partial-length catheter in avoiding UTI are more available to a wider class of patients.

24. Another advantage of the spiraled section of the inflation tube is that it takes up very little space or volume within the lumen of the urinary canal. As such, it does not impede the flow of urine through the urethra. The solid tubular anchor described in the Eshel patents (US 5,916,195 and EP 0 935 977) and in the Rioux patent (US 6,494,855) have the potential to restrict the flow of urine through the urinary canal. In those patents, the interior passageway through the solid tubular anchor is smaller than the cross-sectional area of the urinary canal. As a consequence, urine flow may be restricted. Restricted urine flow can complicate the urinary function of older men, which is naturally diminished because of age. In contrast, the coiled section of the inflation tube does not limit the cross-sectional area of the urinary canal because the urine can flow between the individual coils of the coiled section, with no greater restriction than the amount of area consumed by the inflation tube itself.

25. The solid tubular anchors described in the Eshel and Rioux patents have the potential to irritate and disturb the mucosa of the urethra due to the relatively large surface area contact with the urethra. The large surface contact could lead to irritation, which would enhance the opportunity for germs to interact with the tissue. The large surface area contact could also lead to greater sensation to the user, and could possibly even lead to a low level of pain. A large surface area contact also provides an

opportunity for germs to grow and multiply, because the urine would not appear to contact those germs behind the relatively large surface interface between the tubular anchor element and the mucosa or wall of the urethra. The soft, deformable and compressible coiled section of the inflation tube, which makes very small contact with the mucosa of the urethra as explained above in paragraph 23, offers a greater probability of avoiding the problems of irritation, pain, sensation and infection from germs.

31. I have read US patent 4,531,933 to Norton and US patent 4,813,925 to Anderson, which I will refer to below as the "Norton patent" and the "Anderson patent." I was not aware of the Norton patent at the time that I and Dr. Bolmsjö made the invention described in the above application, but I was aware of stents similar to those described in the Anderson patent as a result of having used those stents in my medical practice for many years. I do not believe that the Norton and Anderson patents lead to the use of the coiled section of the inflation tube as a downstream restraint against upstream movement described in the above patent application. Also, I do not believe that the Norton and Anderson patents would have been significantly useful to a person having skill in the art in this field in making the invention described in the above patent application, even in view of the catheters described in the Eshel patent, in the Rioux patent and in US patent application 2003/0208183 to Whalen.

32. The device is described in the Norton and Anderson patents are stents which are inserted in the ureter between the renal pelvis (kidney) and the bladder to preserve the flow of urine between the renal pelvis and the bladder. Usually stents such as those described in the Norton and Anderson patents are prescribed when some form of urinary disease, typically cancer, causes the ureter to collapse shut or to diminish to a restricted size, or when it is desired to assure that the ureter stays open wide to assist in passing kidney stones or similar obstructions from the renal pelvis.

33. The physiology and physical aspects of urine flow between the renal pelvis and the bladder are substantially different from the physiology and physical aspects of urine flow from the bladder through the urethra to the external opening in the penis.

These differences in physiology and physical aspects of urine flow lead me to conclude that the coils, loops and curls described as the restraints in the ureter stents of the Norton and Anderson patents would not prove useful for restraining the position of a partial-length prostatic catheter of the type described in the above application, for the reasons described below:

a. The ureter has a three layer muscle surrounding it which is similar to the musculature surrounding portions of intestines in the gastrointestinal tract. A neurologic center within the renal pelvis involuntarily stimulates the muscles surrounding the ureter to cause it to constrict in a peristaltic manner at a rate of about three or four times per minute. The peristaltic constrictions progressively push small amounts of urine from the renal pelvis into the bladder. When the peristaltic constrictions do not occur, there are no forces acting on the ureter. The peristaltic action is relatively gentle, at a very low pressure. For example, if a man was placed head down with his lower body angling upward at about a 30° angle, in approximately 20-30 minutes the ureter would be paralyzed and unable to move urine simply because of the pressure differential between the higher bladder and the lower renal pelvis. This demonstrates that very little pressure is present in the ureter and therefore only very small forces are at work during the peristaltic constriction of the ureter which might influence or cause migration of the stents described in the Norton and Anderson patents.

b. On the other hand, the bladder is a very muscular organ which is capable of producing substantial pressure applied to the urine confined within it. The pressure from the bladder is essential to micturation. The bladder pressure causes a stimulus which allows the external urinary sphincter muscle to open and which propels the urine from the bladder through the urethra to the external opening in the penis. The pressure in the bladder pushes the urine through the urethra with considerably greater force than the force generated by the peristaltic movement of the ureter. The pressure in the bladder and from the urine flowing through the urethra slightly distends the urethra causing its size to expand. The peristaltic action of the ureter results in constant changing of the width of the ureter, but the entire ureter is not expanded to a larger-

than-normal size at one time as is the case with the urethra during micturation. Because of the peristaltic action of the ureter, some parts of it are constricted while other parts are expanded. The constricted parts of the ureter should hold the ureter stent in place and restrain its movement while other parts of the ureter are expanded, unlike the entire urethra which is expanded entirely during urination and which might loosen any retention device located within that urethra.

c. For these reasons of physiology and physical aspects of urine flow, the description in the Norton and Anderson patents and the information available to me as a medical doctor indicates that the coils, loops and curls described in the Norton and Anderson patents would not necessarily be effective and reliable as a downstream restraints if located in the urethra for a partial-length prostatic catheter.

34. The physiology and physical forces which act on the stent in the ureter are also substantially different from the physiology and physical forces which act on a partial-length prostatic catheter in the prostatic urethra. Unlike the forces acting on a stent in the ureter, forces act on a partial-length prostatic catheter to migrate that catheter upstream.

a. The involuntary repetitious peristaltic movement of the ureter constricts around the stent at some location along the ureter at all times. That is a consequence of the peristaltic movement, as explained above. Such peristaltic effects are required if the urine is to be pushed through the ureter. The peristaltic constriction around the stent in the ureter should restrain it against movement, and when the peristaltic movement does not occur, there are no forces acting on the ureter, all of which has been explained above.

b. The prostate gland consists of fibrocystic tissue and soft muscular tissue which extends from the bladder. The prostate gland surrounds the prostatic urethra and the partial-length catheter located in the prostatic urethra, as described in the above application. Between each micturation, the muscular tissue of the bladder neck and the prostate gland constricts the prostatic urethra. Normally the bladder neck and the prostatic urethra is completely constricted between each micturation. When a

partial-length catheter is inserted in the prostatic urethra as described in the above application, that partial-length catheter prevents the muscular tissue of the prostate gland and the bladder neck from constricting the prostatic urethra. However, at the downstream end of the partial-length catheter, any small gap between the downstream end of that catheter and the external urinary sphincter muscle provides a small space for the muscular tissue to attempt to constrict the prostatic urethra. That constriction applies a slight force on the partial-length catheter which tends to push it in the direction of the bladder. Movement of the partial-length catheter toward the bladder is also facilitated by the normal physical movement of the user, such as by walking or running. It is for this reason that the partial-length catheter must be restrained against upstream movement.

c. The constriction force from the muscular tissue in the prostate gland is substantially stronger than the more gentle peristaltic forces applied to the ureter. The stronger forces from the prostate gland indicate that a more substantial restraining force is required than the force required to restrain the ureter stents described in the Norton and Anderson patents. These differences in physiology and physical forces lead me to conclude that the coils, loops and curls described as the restraints in the ureter stents of the Norton and Anderson patents would not necessarily prove useful for restraining the partial-length prostatic catheter of the type described in the above application against upstream movement.

35. Both the Norton and Anderson patents describe a hollow interior passageway through the structural bodies of the stents. This hollow interior passageway is to minimize the pressure differential between the renal pelvis and the bladder. An increased pressure differential between ends of the ureter is typically responsible for, or is connected with, obstructions and blockages in the ureter, such as kidney and ureteral stones. By minimizing that differential pressure through the use of the hollow interior passageway, the amount of force required to achieve the peristaltic movement through the ureter while still moving obstructions is diminished. The diminished differential pressure diminishes the amount of restraint required to hold the

stent in the ureter, because there is no significant pressure differential which is attempting to push the stent from the renal pelvis toward the bladder. The differential pressure- relieving interior passageway in the Norton and Anderson patents lead me to conclude that the coils, loops and curls described as the restraints in the ureter stents of the Norton and Anderson patents would not prove useful for restraining the partial-length prostatic catheter of the type described in the above application where no such pressure-relieving passageways are possible or permitted to achieve voluntary control over micturation.

36. The renal pelvis and the bladder have an open volume adjacent to the location where the ureter connects those organs. It appears to me that the restraint described in the Norton and Anderson is achieved primarily because of the large size of the coils, loops and curls at opposite ends of the ureter stent contacting the walls of the renal pelvis and the bladder at the location of the large volume adjacent to the openings to the ureter. The retention occurs by the relatively large coils, loops and curls contacting the wall of the renal pelvis and the bladder adjacent to the openings. The open volume or space in the renal pelvis and kidney is substantially larger than the size of the ureter and the urethra, which indicate that the coils, loops and curls described in the Norton and Anderson patents would not function adequately when placed in the urethra, or even whether they could be placed in the urethra because of their large size.

37. Because of the relatively high pressure on the urine created by the bladder, the partial-length prostatic catheter described in the above patent application must have a substantial upstream restraint against downstream movement. Otherwise, the high-pressure would easily push the partial-length catheter through the urethra. The balloon described in the above patent application creates a substantial upstream restraint because it can be inflated to a size which is effective in restraining downstream movement of the partial-length catheter even in response to the high urine pressure in the bladder. The partial-length catheter cannot be inserted through the urethra into the bladder with the balloon inflated, so some means is required to inflate the balloon once it is in the bladder. In addition, some means to occasionally re-inflate the balloon is

useful, because the balloon may slightly leak some of its pressurizing fluid. The inflation tube described in the above application permits the use of the balloon as the upstream restraint against downstream movement, but that inflation tube must remain extending through the urethra. The Norton and Anderson patents do not describe an inflation tube. There is no need for such an inflation tube in either stent. Because the Norton and Anderson patents have no inflation tube or any structure similar to an inflation tube, they do not suggest to me any applicability or relationship to the type of partial-length catheter that requires an inflation tube and a balloon, such as is described in the above application.

38. The inflation tube described in the above application also permits conveniently removing the partial-length prostatic catheter after the need for its use ends. Pulling on the inflation tube, after releasing the air pressure and collapsing the balloon, allows removal of the catheter. Nothing comparable to the convenience of removal is discussed in the Norton or Anderson patents. The stents described in the Norton and Anderson patents must be removed by a medical extraction procedure that will typically involve the use of an endoscope.

The above statements conclude this Declaration.

Sonny Schelin, M.D., Ph.D.
February 26, 2009

Curriculum Vitae of Sonny Schelin, MD, Ph.D.

Personal Information:

Name: Sonny, Ernst, Gunnar SCHELIN

Address: Snäcköhamn, 380 30 ROCKNEBY. Sweden

Born: 1945

Citizen and Resident of Sweden

Fluent in Swedish and English

Education:

Bachalaureat in Kalmar, Sweden, 1967.

M.D. at University of Lund, Sweden, 1973.

Specialist in General Surgery, Kalmar, Sweden, 1980.

Specialist in Urology, Linköping University, Sweden, 1987.

Ph.D. in Medical Science at University of Lund, Sweden, 2006.

Employment History:

4 years as house-physician (internal medicine) 1972 -1975 in Kalmar.

3 years as assistant surgeon, 1 year as assistant orthopaedic surgeon and 6 months as assistant anaesthetist 1975 – 1979 in Kalmar.

2 years as assistant urologist in the University hospitals in Malmö and Linköping 1977 – 1985.

Senior consultant (general Surgery) at County Hospital, Kalmar 1979 – 1985.

Head and senior consultant (Urology) at County Hospital, Kalmar 1985 – 1993.

CEO and senior consultant in Urology in a private clinic (Specialistläkargruppen i Kalmar AB) since 1993.

Since 1993, senior consultant as operating urologist in Kalmar hospital 1-2 days every week.

Audit Summary:

Since 1993 I have practiced Office Urology 3 days weekly in Specialistläkargruppen in Kalmar. I have seen about 3600 patients every year. Most patients have been referred from general physicians. I have handled almost all patients myself without need for internal consultations. In some rare cases telephone consultations within the group of Urologists organized by Specialistläkargruppen in Kalmar have been practiced.

In Office Urolgy: I am familiar with most of the diagnostic and therpeutic procedures: Cystoscopy, internal urethrotomy, bladder neck incisions in local anaest., transurethral resections of bladder tumors, circumsisions, vasectomies, sclerotherapy or open resection of hydrocele and spermatocele, pressure flow studies, transrectal ultrasound (TRUS) and TRUS - guided biopsies, and Prostalund Feedback Treatment(PLFT® = Core Therm® = TUMT).

In Surgery: I have regularly produced all types of endo-urological procedures for almost 25 years (TURP, TURB, TUIP and diagnostic and therapeutic uretroscopies). I have performed more than 500 open radical prostatectomies since 1986.

Minimal invasive surgery: See above. I am one of the inventors of the PLFT®/Core Therm®. It is a new mode of TUMT with a temperature feedback system making it possible to individualize the treatment. In Scandinavia it is now used in several hospitals and University hospitals as a new "gold standard" as an alternative to BPH surgery. I have experience from more than 500 outpatient PLFT®/Core Therm® treatments. I am also the inventor of the "Schelin catheter®", a new device making it possible to inject medications transurethrally into the prostate, e.g. local anaesthetics + Epinephrine prior to PLFT and TURP. I am also one of the inventors of the "Core Flow Soft Stent™", a temporary prostate short catheter stent to be used as an alternative to an indwelling full length catheter for prostate obstruction.

Medical Professional Associations:

I am one of the organizers of a Scandinavian urology conference – "The Kalmar union," which has conducted meetings for the last 15 years.

I am a member of the Swedish Association of Urology and have been since 1985 and was a board member 1999 – 2001.

I am a board member of the Swedish Association of Private Urology and have been for the last 3 years.

PhD Thesis:

Development of Feedback Microwave Thermotherapy in Symptomatic Benign Prostatic Hyperplasia. Defended at Faculty of Medicine, Lund University: 10th of March 2006.

Inventions

I am the named inventor or coinventor of the following 8 granted US patents and published US patent applications, including the above application, all of which relate to urological treatment and techniques for facilitating urine drainage:

1. US Patent No. 7,041,090 - "Method and Apparatus for Self-Draining of Urine"

2. US Patent No. 6,852,105 - "Method and Apparatus for Insertion of Self-Draining Urine Apparatus into Bladder

3. US Patent No. 6,626,876 - "Method and Apparatus for Self-Draining of Urine"

4. US Patent No. 6,524,270 - "Method and Device for the Treatment of Prostate Tissue"

5. US Patent Application 2006/0111691- "Partial Length Indwelling Urinary Catheter and Method Permitting Selective Urine Discharge"

6. US Patent Application 2005/20080399- "Urinary Catheter and Method with Increased Resistance to Obstructions"

7. US Patent Application 2005/0059929- "Partial Length, Indwelling Prosthetic Catheter Using Coiled Inflation Tube As an Anchor and Methods of Draining Urine and Flushing Clots"

8. US Patent Application 2005/0124852-"Method and Device for the Treatment of Incontinence" (now abandoned)

Patents and patent applications corresponding to these US patents and patent applications have been granted and filed in many countries outside of the United States.

Publications:

Sturfelt G, **Schelin S**: Acute effects barbiturates in Parkinson´s disease. A preliminary communication with case reports. Acta Med Scand. 1977 Jan;201(-2):75-6.

Schelin S: Observations on the effect of metoclopramide (Primperan) on the human ureter. A preliminary communication. Scand J Urol Nephrol. 1979;13(1):79-82.

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Hugosson J, **Schelin S**, et al: The risk of malignancy in the surgical margin at radical prostatectomy is reduced almost three-fold in patients given neoadjuvant hormone treatment. Eur Urol. 1996;29(4):413-9.

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